



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

M 870 N

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

April 29, 1997

97-PHI-25

William Schultz, President
Eastern Home Care & Oxygen Co.
31 E. Fifth Street
Mt. Carmel, PA 17851

GEN.

SPEC.

RELEASE

F# _____ DATE _____

Reviewed by: Wm. W. Knipe

Dear Mr. Schultz:

On March 3, 1997 your medical oxygen transfilling facility at 679 S. Church Street, Hazleton, PA was inspected by Investigator Carol Rehkopf of the U.S. Food and Drug Administration. At the conclusion of the inspection she discussed her findings listed on FDA form FD-483 with Thomas Brokenshire, Director of Operations. A copy is enclosed for your reference. This form lists deviations from the regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations (21CFR). Consequently, your product, oxygen, USP, is misbranded within the meaning of Section 502 of the Federal Food, Drug and Cosmetic Act (the Act) as described below:

o All medical oxygen cylinders must be clearly labeled. Several D and E size cylinders and cryogenic home vessels released for distribution were observed to have no labels. Also, a number of cylinders and cryogenic home vessels were found to have labels too badly worn to be legible. These articles are misbranded within the meaning of section 502(f)(1) of the Act in that they are a prescription drug and do not bear adequate directions for use [21 CFR 2201.100(c)]; and section 502(g) of the Act in that the labeling fails to indicate whether or not the oxygen has been produced by an air liquifaction process as required by the United States Pharmacopeia.

We also note the following, labels for both medical and industrial oxygen were stored in the same cabinet. You should control the storage of medical and industrial oxygen labels in a manner that will preclude a mixup of these labels. Also, you should have an approved master copy of medical oxygen labels on file.

Training should be documented. Even though workers learn the duties on the job, you should document that training as a record of proficiency. This documentation is especially critical in learning

bcc: W/L File, Legal File, EF, HFR-MA100, HFR-MA 150, HFA-224, HFC-110, HFD-322(DSylvia), HFC-240, HFI-35(redacted), HFR MA-1510, WL Book, Dist. MAZ
CFN:2529580

William Schultz, President
Page 2

to operate the Servomex oxygen analyzer and recording of data on your Lot Number Log Sheet.

This is not intended to be a comprehensive listing of the deficiencies discovered at your firm. It is your responsibility to assure that your company's operations at the Hazleton, PA facility and all other locations under your firm's control are in compliance with the Act and the associated implementing regulations. We request that you notify this office in writing, within fifteen (15) working of your receipt of this letter, of the specific steps you have taken to correct these violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the correction will be completed. Failure to make corrections may subject your products to further regulatory action. These actions include seizure and/or injunction.

Enclosed is a copy of the paper, "Fresh Air" which covers the requirements for filling liquid and gaseous medical oxygen containers. I am sure you will find this helpful in staying abreast of the regulations. Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,


Diana J. Kolaitis
District Director

Enclosure

cc: Thomas D. Brokenshire
Director of Operations
Eastern Home Care & Oxygen Co.
679 S. Church Street
Hazleton, PA 18201

Pennsylvania State Dept of Health
Health and Welfare Building
7th and Forster Streets
P.O. Box 90
Harrisburg, PA 17120
Attn: Division of Primary Care and Home Health Service
Robert E. Bastian, Director